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Datasheet for the decision of 10 July 2009

T 0803/07 - 3.2.02 Case Number:

Application Number: 00986453.9

Publication Number: 1239787

IPC: A61B 18/14

Language of the proceedings: EN

Title of invention:

Apparatus for thermal treatment of an intervertebral disc

Applicant:

Covidien AG

Opponent:

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 84

Keyword:

"Clarity (yes)"

"Novelty, inventive step (yes, after amendment)"

Decisions cited:

Catchword:



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Boards of Appeal

Chambres de recours

Case Number: T 0803/07 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 10 July 2009

Appellant: Covidien AG

Victor-von-Bruns-Straße 19

CH-8212 Neuhausen am Rheinfall (CH)

Representative: HOFFMANN EITLE

Patent- und Rechtsanwälte

Arabellastraße 4

D-81925 München (DE)

Decision under appeal: Decision of the Examining Division of the

European Patent Office posted 24 November 2006

refusing European patent application

No. 00986453.9 pursuant to Article 97(1) EPC.

Composition of the Board:

A. Pignatelli

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Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal on 15 January 2007 against the decision of the examining division posted on 24 November 2006 to refuse the application. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 4 April 2007.
- II. The application was refused for lack of clarity and novelty of the claimed subject-matter vis-à-vis the disclosure of document D1.
- III. Documents cited in the search report:

D1 = WO - A - 98/17190

D2 = US - A - 5 571 147

D3 = WO - A - 99/34860.

- IV. In response to the communications of the Board of 26 March and 16 June 2009 the appellant requested by letter dated 16 June 2009, as a main request, that a patent be granted on the basis of the following version:
 - claims: 1 to 10 filed with the letter of 16 June 2009;
 - description: pages 1 to 6 and 14 filed with the letter of 16 June 2009, and pages 7 to 13 and 15 as published;
 - Figures: sheets 1/2 and 2/2 as published.

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V. Claim 1 of the main request reads as follows:

"An apparatus for treating an intervertebral disc having an inner nucleus pulposus and an outer annulus fibrosus, which comprises: a thermal probe (16) defining proximal and distal ends and having a guidable region (184) adjacent the distal end thereof, the thermal probe (16) being adapted for connection to a thermal energy source (40) to provide thermal energy to the annulus fibrosus to alleviate pain associated with the intervertebral disc, characterized in that the guidable region (184) has sufficient rigidity to advance within the annulus fibrosus of the intervertebral disc in response to an axial force exerted on the proximal end of the thermal probe (16) while having sufficient flexibility to substantially follow and conform to an azimuthal course defined by the natural striata of the annulus fibrosus."

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Amendments

Claim 1 has been correctly recast and delimited having regard to the disclosure of D1 and the description has been adapted to the claim. The amendments, therefore, comply with the requirements of Rule 29(1) EPC 1973.

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3. Clarity

In the decision under appeal it was stated that the claimed feature:

"the guidable region (184) has sufficient rigidity to advance within the annulus fibrosus of the intervertebral disc in response to an axial force exerted on the proximal end of the thermal probe (16) while having sufficient flexibility to substantially follow and conform to an azimuthal course defined by the natural striata of the annulus fibrosus"

was not clear, since the consistency of the anatomical structures varies greatly, e. g. in relation to the age of the individual.

The Board disagrees on these findings. While it is true that the consistency of the vertebral column can vary with the age of the individual, however, for one individual of a given age the consistency of the vertebral tissues varies very little within known range values, from which it results that the rigidity needed for the guidable region of the thermal probe may be easily determined by a skilled person. Therefore, in the Board's view, the clarity of claim 1 is not objectionable.

4. Novelty

D1, see in particular Figures 3, 4, 13 and 15, page 8, line 1 to 8, page 20, lines 20 to 32, page 46, lines 3 to 7, discloses an apparatus for treating an intervertebral disc having an inner nucleus pulposus

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and an outer annulus fibrosus, which comprises a thermal probe 14 defining proximal and distal ends and having a guidable region 16 adjacent the distal end thereof, the thermal probe being adapted for connection to a thermal energy source to provide thermal energy to the annulus fibrosus to alleviate pain associated with the intervertebral disc, in accordance with the preambule of claim 1 at issue.

However, D1 does not disclose the characterizing features of the claim, according to which the guidable region has sufficient rigidity to advance within the annulus fibrosus of the intervertebral disc in response to an axial force exerted on the proximal end of the external probe while having sufficient flexibility to substantially follow and conform to an azimuthal course defined by the natural striata of the annulus fibrosus.

As a matter of fact, the description of D1 repeatedly states that the guidable region advances first through the nucleus pulposus and then along the inner wall of the annulus fibrosus, but without sufficient penetration ability to pierce and to be further advanced through the annulus fibrosus. Therefore, the guidable region of the probe of D1 is unable to be advanced within the annulus fibrosus, let alone between the natural striata thereof (see for example: page 6, lines 27-29; from page 8, lines 30 to page 9, line 1; from page 20, line 26 to page 21, line 9; and from page 22, line 19 to pages 23, line 2).

It results that the subject matter of claim 1 is novel over D1.

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5. Inventive step

Starting from D1 in which the guidable region of the thermal probe does not follow an azimutal course defined by the natural striata of the annulus fibrosus, the problem underlying the invention has to be seen in providing an alternative way of treating the intervertebral disc.

The solution provided by the invention consists in providing the guidable region with sufficient rigidity to advance within the annulus fibrosus of the intervertebral disc in response to an axial force exerted on the proximal end of the thermal probe while having sufficient flexibility to substantially follow and conform to an azimuthal course defined by the natural striata of the annulus fibrosus.

The available state of the art does not to provide any indications which can lead the skilled person in the field in an obvious way to the claimed invention.

In the contested decision it was submitted that in D1 the consistencies of the annulus fibrosus and of the nucleus pulposus could not be clearly distinguished from each other and that Figure 4 showed a probe advanced within a transition zone comprising the annulus fibrosus (see D1, page 17). This could at first sight suggest the claimed invention.

However, the Board observes that it cannot be derived from Figure 4 that the probe is advanced within the annulus fibrosus. The dotted area shown in Figure 4

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refers to the nucleus pulposus which partly extends, due to a degenerative process, beyond its original boundaries within the annulus fibrosus area, as illustrated by the fissure or tear 44. But principally the depicted probe slides along the inner wall of the annulus fibrosus and not into the azimutal striations of fibers within the annulus, as already demonstrated in point 4 above. Therefore D1 does not suggest the solution as claimed.

D2 refers to the thermal denervation of an intervertebral disc while D3 concerns a medical needle or cannula including a rigid bent tip. None of these documents discloses or suggests a solution having the features as claimed.

Accordingly, the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC. Claim 2 to 10 are dependent on claim 1 and, therefore, are acceptable as well.

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Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

The case is remitted to the first instance with the order to grant a patent on the basis of the following version:

- claims: 1 to 10 filed with the letter of
16 June 2009;

- description:
 pages 1 to 6 and 14 filed with the letter of
 16 June 2009, and pages 7 to 13 and 15 as published;

- Figures: sheets 1/2 and 2/2 as published.

The Registrar: The Chairman:

D. Sauter M. Noël